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Venus Legacy User Manual

1. Before You Start

Glossary of Symbols Used in this Manual

The following are symbols that you will find throughout this operating manual and their meanings:

	WARNING sign: The information stated where you will see this symbol is extremely important and must be noted!
Note	Provides general information that is important to keep in mind.
X	Waste of Electrical and Electronic Equipment (WEEE) Marking.
	Fuse.
×	Type BF Equipment.
Μ	Manufacturer.
EC REP	Obelis S.A.
P Authorized Representative in the European Community.	
	Manufacturer (accompanied by the name and address of the manufacturer).
	Date of Manufacture.
F	Symbol used with a HF isolated patient circuit.

	Consult Instruction for Use.
((⊷))	System that includes RF transmitters or that applies RF electromagnetic energy for diagnosis or treatment.

0

Model: Venus Legacy

50-60 Hz.

670VA

Fuse: T10A, 250V

S/N: LE2XXXXX

P/N: LE100004

Power: 100V ~

VENUSCONCEPT

S/N Label



Figure 1-1, Venus Legacy 100V - Serial Number Label



Figure 1-3, Venus Legacy 120V - Serial Number Label

Figure 1-2, Venus Legacy 100V - Serial Number Label

MADE IN ISRAEL

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achemesh Street bld. 62, 1652 Karmiel



Figure 1-4, Venus Legacy 120V - Serial Number Label

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Figure 1-5, Venus Legacy 240V - Serial Number Label



Figure 1-6 Venus Legacy 240V - Serial Number Label



Read the User Manual instructions carefully before installing or using the System to become familiar with all safety requirements and operating procedures thereby prevent accidents, injury and reduce the risk of damaging the machine.

The Venus Legacy is designed for professional use only. The manufacturer cannot be held responsible for damage or injury caused by improper use or for uses other than those for which this machine is intended.

2. Introduction

View of Venus Legacy System



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- a. LF1 Applicator. (detachable accessory)
- b. LB1 Applicator. (detachable accessory)
- c. LF2 Applicator. (detachable accessory)
- d. LB2 Applicator. (detachable accessory)
- e. LF1 Holder.
- f. LB1 Holder.
- g. LF2 Holder.
- h. LB2 Holder.
- i. LF1&LB1 Cables' Pillar.
- j. LF2&LB2 Cables' Pillar.
- k. LF1 Applicator Socket.
- I. LB1 Applicator Socket.
- m. LF2 Applicator Socket.
- n. LB2 Applicator Socket.
- o. Touch Screen.
- p. Emergency button.
- q. Serial Number Label.
- r. On/Off Switch.
- s. Power Socket.
- t. Air Filters unit.

Legacy Applicators(Accessory):

- a. LF1 Applicator Treatment Applicator with integrated thermometer.
- b. LB1 Applicator Treatment Applicator with integrated thermometer.
- c. LF2 Applicator Treatment Applicator with 4 suction levels (optional) and integrated thermometer.
- d. LB2 Applicator Treatment Applicator with 4 Suction levels (optional) and integrated thermometer.

System Description

The Venus Legacy is a non invasive medical aesthetic device with a solution for face and body contouring via Skin Tightening, Temporary Circumferential Reduction, Cellulite Reduction and Wrinkle Reduction.

Venus Legacy is a computerized system generating RF energy which are emitted into the skin.

The Venus Legacy the effects of Multi-Polar array of bipolar RF currents. The energies supplement each other to provide optimal treatment results with minimal risk of side effects.

RF energy heats the tissue to trigger collagen remodeling for the treatment of wrinkles and rhytides.

The system offers 2 main applicators and 2 optional applicators for small and large areas:

- ► LF1 Applicator.
- ➤ LB1 Applicator.
- LF2 Applicator.
- ➤ LB2 Applicator.

Programs that employ **technology** and use LF1, LB1, LF2 and LB2 Applicators are operator dependent. They are designed to treat large and small treatment areas, and the operator can determine the optimal parameters according to specific needs of the client. This can be done by increasing or decreasing not only the treatment time and the interval timer (Page 5-7), but also the energy percentage used during the treatment. As a result, the operator can create tailor-made treatments.

Optional Programs that employ **Suction** and use LF2 and LB2 are operator dependent. They are designed to treat large and small treatment areas, and the operator can choose one out of four suction levels according to specific needs of the client.

Intended use:

2-3

- Increase of Skin Tightening.
- Temporary Circumferential Reduction.
- Cellulite Reduction
- Wrinkle Reduction

Intended user and environment:

- The device is intended to be used by professional practitioners in the medical aesthetic field.
- The operator should stand near the client.
- The operator is not allowed to leave a client during the entire treatment.

3. Safety

2-4

This chapter describes safety issues regarding the use and maintenance of the System, with special emphasis on electrical safety.



Please carefully read this chapter and be familiar with all of its safety requirements and operating procedures prior to operating the System.

Introduction

The System is designed for a safe and reliable treatment when used in accordance to proper operating and maintenance procedures as outlined in this operating manual. Only trained and qualified personnel, by an authorized trainer, can use the system and perform the treatments. The operator and all other personnel operating or maintaining the System should be familiar with all of the safety information provided in this manual.

The primary objective should always be in maximizing the safety of both the client and the treatment operator.



The Operator

- All operators MUST be familiar with the system controls and know how to shut down the system in case of trouble.
- Always be aware of the possible dangers of using the System and take proper precautions as described in this manual.
- Do not touch the inner parts of the System. The System services and repairs must be performed by qualified personnel only. Failure to do so will void all service agreements.
- High voltage is present inside the System, do not attempt to open the casing.
- Disconnect the System from the power supply before servicing (pull out the plug).

- > Do not use the System unless all enclosure panels are properly in place.
- > Do not tamper with the contro $_{3-1}$ attempt to open up the System.
- Do not abuse, sit or lean on the system.
- > Venus Legacy System should be kept out of the reach of Children.
- Do not allow the LF1, LB1, LF2 & LB2 Applicators to come in contact with metal elements - this could damage the electrodes.
- A patient history should be completed prior to treatment to ensure no complications could arise. It is important to verify client does not full under the exclusion criteria.
- The PATIENT should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth (for example operating table supports, etc). The use of antistatic sheeting is recommended for this purpose.
- The cables to the Applicators should be positioned in such a way that contact with the PATIENT or other leads is avoided.
- > The product should not be in contact with other equipment.
- Failure of the System could result in an unintended increase of output power.
- Interference produced by the operation of HF SURGICAL EQUIPEMENT may adversely influence the operation of other electronic EQUIPEMENT.
- For PATIENT with cardiac pacemakers or other active implants, a possible hazard exists because interference with the action of the pacemakers may occur, or the pacemaker may be damaged. In case of doubt, approved qualification advice should be obtained.
- This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures. Such as reorienting or relocating.
- Portable and mobile RF communications equipment can affect the System.
- The client should then be fully informed of the treatment protocol, expected results and should sign informed consent form prior to beginning treatments.
- Only authorized person is allowed to stand near the system during the treatment.
- Stop the treatment in case of unexpected changes in client's condition.
- Do not drop the Applicators. In case the Applicators were dropped, turn off the system immediately. Don't use the broken applicator and call to

local service support.

Emergency button should be used in case of emergency for client or in Case of deterioration of a client's condition. Operator should explain to the client the use of Emergency Button.

A Electrical and Mechanical Safety

- Keep all covers and panels of the System closed. Removing the covers/panels will not only create a safety hazard but will also affect your service agreement.
- > Keep your hands away from the Applicators during the System start-up.
- Perform maintenance procedures only when the System is shut down and power source has been disconnected.
- Do not place the System at working position at the floor with slope of more than 5°.
- Do not use the applicator if its cable is loose or broken.
- When moving the System, do so carefully and slowly to ensure no damage will be made to the System or the operator.
- The System is grounded through the grounding conductor in the power cord. This protective grounding is essential for safe operation.

 \triangleright



Fire Hazards

- Do not use the System in the presence of explosive or flammable materials.
- > Do not use flammable substances when preparing the skin for treatment.
- If germicide swipes is used for cleaning and disinfecting the system, it must be allowed to fully dry before the System can be used again.

4. System Installation

The System is designed for installation in an medical aesthetic environment. To install the System, please follow the instructions listed below:

- 1. Inspect the original packaging prior to opening to insure that during transportation, no damage was done to the outer carton layer and the anti-shock sticker (Damaged = Red indicator). Then continue by unpacking the System carefully.
- 2. Check the System and all of its components for visible damage that could have been done during transport.
- **3.** Do not position the system in a way that will make it diffucultto connect/disconnect the power cable.
- 4. Connect the Applicators holders.
- 5. Connect the LB1, LF1, LB2 and LF2 Applicator connectors to the rear panel of the system. This is done by aligning the guiding pins on the LB1, LF1, LB2 and LF2 Applicators connector with those on the rear panel of the System. Then slide the connector along the guiding pins until it clicks into place and turn clockwise to lock the connector. Each connector has its own port and will be labeled accordingly.
- 6. Close the connectors cover
- 7. Place the Applicators in the appropriate holders.
- 8. Place the Applicators cables in the appropriate cable pillars.
- 9. Connect the Power Cord to the back of the System.
- 10. Plug the System Power Cord into an appropriate electrical outlet.

Equipment List

The System includes the following:

- System platform (Venus Legacy).
- Power cord.
- LF1 Applicator.
- LB1 Applicator.
- LF2 Applicator.
- LB2 Applicator.
- User Manual.
- > Quick reference guide (only for non-English speakers' countries).

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Measurement tape. Electrical Requirements

The System can automatically accommodate the most of the local mains voltage. Specifically, the System can be energized of the mains voltage as follow: Single phase 100/120/240V~; 50-60Hz. 10A



For continued protection against fire, only fuses that are defined on the System label can be insulted in the System. Only power cord which is suitable to be connected to the System and approved for the local mains, must be used.

Environmental Requirements

- Corrosive materials can damage electronic parts, ensure that the environment is free from corrosive material.
- > Metallic dust can damage electrical equipment.
- For optimal operation, the System should be placed in a room with temperature between 10°- 35°C (50°-95°F) with a relative humidity of less than 80% and altitude up to 3000m.
- For optimal storage, system should be stored in a place with temperature between -20 to 55°C (-13 to 131°F) with a relative humidity of 0-90 % @ 55°C noncondensing. For Optimal transportation system should be transport under the temperature range between -10°- 60°C (14°-140°F) with a relative humidity of less than 80% and altitude up to 15000m.

Moving the System

Within the facility:

- > Turn the System off.
- > Disconnect the Power Cord.
- > Place the Applicators into their dedicated holders.
- Release the wheel brakes.
- > Carefully push or pull the system to its designated area

To another facility:

- > Turn the System off.
- Disconnect the Power Cord.
- > Disconnect the Applicators and pack them into their original storage case.
- Disconnect the Applicators holders.

- > Disconnect the Applicators cables pillar.
- Release the wheel brakes.
- If the shape of the floor has the angle of 10 degrees or more than System should be transported with backside handle forward.
- Carefully push or pull the system always carefully lifting it and placing it on its backside handle for transportation.

Upon arrival to the new facility:

- > Slowly push or pull the System into place, using the back and front handles.
- Reconnect the Applicators holders.
- > Reconnect the Applicators cables holders.
- Reconnect the Applicators.
- > Reconnect the Power cord and turn the System on.



- Never lift, pull or push the System using the touch panel. Always use the handles when moving it.
- The System can be left unattended at a slope of 5 degrees in all directions as long as the wheels are locked. Over a 5 degree slope of, the device must be under supervision.

5. Operating the System

Turning the System On/Off

Before turning the System "ON", verify that the power cord is connected to the inlet located on the rear panel of the system and to the main power outlet.

Switch on the system by turning the "ON/OFF" button located in the rear panel of the system to its "ON" position or "1". Within 50 seconds the Login Screen (See Figure 5-1) appears.

Login Screen

After system has been switched on, the Login Screen (See Figure 5-1) will appear. In order to avoid unauthorized users from accessing system, authorized operator needs to enter his 8 digit / character code and press Confirm button (see Figure 5-1 circled in red).

Initial Login code is supplied with the installation documents.

It is recommended to change initial Login code, using Set Login Code option in Tools Menu (page 5-14).

After the Confirm button is pressed, the Menu screen appears.



Figure 5-1: Login Screen

Menu Screen Options

The **Treatment** Screen is the system main screen (See Figure 5-2). Treatment is initiated on this screen. The **Tools** screen is accessed from the Treatment screen.

In order to perform a treatment, the operator needs to follow the steps below:

- Select the desired Applicator (LB1, LF1, LB2 or LF2), according to treatment area, by pressing on one of the arrows, forward of backwards (See Figures 5-2 circled in red).
- 2. Adjust treatment parameters.
- 3. Adjust Interval Timer (optional).
- 4. Initiate treatment.



Figure 5-2: Treatment Screen

Treatment

Selecting Suitable Applicator

Before the treatment, the operator must select the desired applicator, according to the size of the treatment area. The LB1 & LB2 Applicators are used for the treatment of large areas as they have more coverage. The LF1 & LF2 Applicators are used for the treatment of smaller areas. Selecting the suitable applicator is done by pressing on one of the arrows, forward of backwards (see Figures 5-3 - 5-6, circled in red). The system default applicator is the LF1 applicator.





Figure 5-6: Treatment Screen (LB2 Applicator Selected)

Adjusting Output Power

Output Power is measured in percent's of Maximum power. It is adjusted by pressing the "+" & "-" buttons located on the screen next to the *peripheral icon* (See Figures 5-7 & 5-8, marked in red) or the *internal icon* (See Figures 5-9 & 5-10, marked in red). Adjustments are in one-percent increments.

The total Output Power is 150W RF

The **Output Power** can be set between 0-100 percent, whereas 0% is equivalent to zero (no) RF output, and 100% is equivalent to 135W RF output (maximum RF output of the system) The **internal Output Power** can be set between 0-100 percent, whereas 0% is equivalent to zero (no) RF output, and 100% is equivalent to 15W RF output. Correlation between energy percent and output power is linear. This parameter can be increased and / or decreased during treatment, as long as the patient feels comfortable.

Pressing the **peripheral** *icon* (See Figure 5-8, circled in red) or the **internal** *icon* button (see Figure 5-10, circled in red) will reset output power to zero.



Figure 5-7: Treatment Screen





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Adjusting Suction Level

The suction technology/option is available for treatments with LF2 & LB2 Applicator. The system offers 3 suction levels; it is adjusted by pressing the icon, representing the desired suction level (See Figures 5-11 & 5-12, circled in red). Pressing on active suction level (See Figures 5-13, circled in red) will disable this option.



Figure 5-13: Active/Non Active Suction option

Temperature Profile Indicator

The LF1, LB1, LF2 & LB2 Applicators have an integrated thermometer which can give an indication to the operator, of the patient's skin temperature.

The temperature is presented in real-time in 2 ways:

- 1. Numerical indication (See Figure 5-14, circled in red) shows the average of client's 5 latest skin temperature samples at a second. Pressing on the temperature icon, will switch between Celsius indication and Fahrenheit indication.
- 2. Graphical indication (See Figure 5-15, circled in red) shows the client's skin temperature continuously.









- 3. The integrated temperature measurement tool should be used as an indicator only and cannot replace an external thermometer.
- 4. External Thermometer should be used during the entire procedure

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Adjusting Treatment Time

Treatment Time is measured in minutes. It is adjusted by pressing the "+" & "-" buttons located on the screen next to the clock icon (see Figures 5-16 & 5-17). Adjustments are in one-minute increments.

Treatment Time is set between 0-30 minutes.

This parameter can be increased and / or decreased during the treatment. Pressing the *Clock* button (See Figure 5-17, circled in red) will reset Treatment Time to zero.





Figure 5-16: Treatment Screen

Figure 5-17: Adjusting Treatment Time

Interval Timer

This feature is for optional use, for the purpose of dividing full treatment time into time intervals (time segments). This can be convenient when dividing a full treatment area into a few smaller treatment zones.

The **Interval Timer** (see Figures 5-18 & 5-19, marked/circled in red)) begins countdown when treatment is initiated and beeps when timer is zeroed. It then begins countdown again. This process repeats itself as long as treatment is undergoing.

Interval Time is adjusted according to the treatment time required for each small treatment zone (as opposed to the total Treatment Time, discussed in chapter 5.4.3 above).

It is set between 0-30 minutes, and adjusted by pressing the "+" & "-"buttons located on the screen next to the *Interval Timer* button (see Figure 5-19, circled in red). Adjustments are in 15 seconds steps.

The **Countdown Timer** (see Figure 5-19) begins countdown when treatment is initiated and beeps when timer is zeroed.

Pressing the *Interval Timer* button (see Figure 5-19, circled in red) will synchronize the Countdown Timer with the Interval Time.



Figure 5-18: Treatment Screen



Figure 5-19: Interval Timer

Countdown Timer

Initiating (Starting) Treatment, Pausing and Stopping a Treatment

Once **Treatment Time**, **peripheral Output Power**, **internal Output Power** and **suction level** parameters are set, the operator should hold the selected applicator and press the *Start* button located in the lower right corner of the **Treatment** Screen (See Figure 5-20, circled in red). This will emit peripheral and/or internal and/or suction, via the selected applicator, and the treatment can begin.

The color of *Start* button will turn from blue to green (see Figure 5-21, circled in red) and will flash as long as system is active (generating RF). **Treatment Time** and **Countdown Timer** (if used) will start countdown .



Figure 5-20: Treatment Screen



Figure 5-21: Treatment Screen - system is active

During the treatment, pressing the *Pause* button (see Figure 5-22, circled in red) will pause the treatment. When paused, the treatment parameters will not be reset, but the system will not emit RF from the Applicators. The *Pause* button will turn <u>red</u>. Pressing the *Start* button again will resume the treatment.

Pressing the *Stop* button (see Figure 5-23) will end the treatment. An "End of Treatment" Information Box will appear (See Figure 5-24), and treatment parameters will be reset to zero.



Figure 5-22: Treatment Screen -Pause Button



Figure 5-23: Treatment Screen -Stop Button



Figure 5-24: Information Box "End of Treatment"

Control Switch Button

The "control switch" button (See Figure 5-25, circled in red) allows the user to alternate between two modes: "screen mode" (See Figures 5-26 & 5-27), where the system is controlled by pressing the buttons on the screen; and "Applicator mode" (See Figures 5-28 & 5-29), where the machine is controlled by pressing the buttons on the Applicator.



Figure 5-25: Control Switch Button



Figure 5-26: Control Switch Button; Screen Mode - LF2 Applicator



Figure 5-27: Control Switch Button; Screen Mode - LB2 Applicator



Figure 5-28: Control Switch Button; Applicator Mode - LF2 Applicator



Figure 5-29: Control Switch Button; Applicator Mode - LB2 Applicator

The "control switch" button will only appear on the screen when the LF2 or LB2 Applicators are chosen and the default choice is "screen mode" (See Figures 5-30 & 5-31, circled in red).



Figure 5-30: Control Switch Button Treatment with LF2 Applicator



Figure 5-31: Control Switch Button Treatment with LB2 Applicator

The functionality of the "control switch" will change in conjunction with the Applicator used:

LF2 Applicator: pressing the "control switch" button will shift control to "Applicator mode" and via the buttons on the Applicator, the treatment can be started or stopped. During the treatment, the RF and suction intensity, the treatment time, the pause button and the stop button are controlled via the screen. Pressing the "control switch" again will shift control back to the screen.

LB2 Applicator: pressing the "control switch" button will shift control to "Applicator mode", and via the buttons on the Applicator, the RF and suction intensity can be adjusted and the treatment can be started or paused. During the treatment, the treatment time, the pause button and the stop button are also controlled via the screen. Pressing the "control switch" again will shift all control back to the screen.

Tools

When pressing the **Tools** button (see Figure 5-28, circled in red) in **Treatment** screen, the **Tools** screen will appear (see Figure 5-29) enabling operator to personalize the system, and enabling a Venus Concept technician to update the system software, calibrate the screen and more.



Figure 5-32: Treatment Screen Tools button



Figure 5-33: Tools Screen

Changing Languages

Pressing the *Language* button (See Figure 5-34, circled in red) will change the language of the system software. The operator can choose between different languages. Activating the selected language is done by pressing the *Confirm* button (bottom right corner of the screen).

English is the default language of the Venus Legacy system.



Figure 5-34: Tools Screen- Language button

Setting the Volume Level of the System Speakers

Pressing the *Volume* button in the **Tools** Screen (See Figure 5-35, circled in red) will open a Volume Screen, enabling the operator to set the volume of the system's speakers.

Volume is defined in percentage between 0-100 (whereas 100% indicates maximum volume). Pressing the "+" and "-" buttons (See Figure 5-36) followed by pressing the *Confirm* button, will increase and decrease the volume level of the system accordingly.

Pressing the *Volume* button (See Figure 5-36, circled in red) will mute the system (i.e. set speakers' volume to zero).



Figure 5-35: Tools Screen - Volume button

Figure 5-36: Volume Screen

Set Login Code

In order to change the Login Code, the operator has to press the **Set Login Code** button in Tools screen (See Figure 5-37, circled in red). The **Login Code** is changed in three steps, using three screens:

- I. Operator is required to enter current Login Code (followed by pressing **Confirm** button) See Figure 5-38.
- II. Operator is required to enter a new Login Code (followed by pressing **Confirm** button) See Figure 5-39. The Login code must consist of 8 digits / characters.
- III. Operator is required to re-enter the new Login code (followed by pressing the *Confirm* button) – See Figure 5-40.



Figure 5-37: Tools Screen - Set Login Code Button



Figure 5-38: Setting Login Code (Step I)





Figure 5-39: Setting Login Code (Step II)

Figure 5-40: Setting Login Code (Step III)

Logout

Pressing the *Logout* button (See Figure 5-41, circled in red) will lock the system and prevent unauthorized access. The **Login** Screen will appear, requiring operator to reenter their Login code.



Figure 5-41: Tools Screen - Logout button

Set Auto Logout Time

Pressing the **Set Auto Logout Time** button in **Tools** Screen (see figure 5-42, circled in red) will open a **Set Auto Logout Time** Screen, enabling operator to set the time after which the system will logout automatically if the screen has not been activated.

The **Auto Logout Time** is set between 0:15-4:00 hours, in 1 minute increments and adjusted by pressing the "+" & "-" buttons (See Figure 5-43).

Pressing the **Set Auto Logout Time** button (See Figure 5-43, circled in red) will set the **Auto Logout Time** at 15 minutes.





Figure 5-42: Tools Screen - Set Auto Logout Time Button

Figure 5-43: Set Auto Logout Time Screen



System will automatically Logout if Screen has not been activated for 30 minutes.

System Information

Pressing the *Information* button in **Tools** Screen (see Figure 5-44, circled in red) will open an **Information** Screen (see Figure 5-44), enabling operator to see the system information such as Software Version and system Serial Number.



Figure 5-44: Tools Screen - Information Button

Figure 5-45: Information Screen

Technician Mode

The **Technician Mode** button is located in the **Tools** screen (See Figure 5-46, circled in red) and should be operated by Venus Concept authorized technicians only. It is password protected, and cannot be accessed.



Figure 5-46: Information Tools Screen -Technician Mode Button

Activation Period

The Activation Period is an optional feature of the Venus Legacy system.

This feature allows system operation for a limited period, referred to as "Activation Period".

If the *Activation Code* button (a <u>green</u> button) appears on the **Tools** screen (See Figure 5-47 & 5-48, circled in red), the *Activation Period* feature is activated (is ON) and system operation is limited to a pre-determined date (referred to as "*Expiration Date*"), or to pre-determined *Operation Time*, after which system will be deactivated.

If an **Expiration Date** appears on the bottom of the **Tools** screen (See Figure 5-47, circled in red), the system is limited by a pre-determined date ("**Expiration Date**"), and will be deactivated after this date.

If Remaining **Operation Time** appears on the bottom of the **Tools** screen (See Figure 5-48, circled in red), the system is limited to pre-determined **Operation Time** (hours).

If the *Activation Code* button does <u>not</u> appear on the **Tools** screen (See Figure 5-49), the **Activation Period** feature is OFF, and the system is 'open' for use and not limited by time or date.



Figure 5-47: Tools Screen - Activation Period is ON (date limited)

English	Volume	Set Login Code	Logout	Set Auto Logout Time	I formation
Technician Mode	Colvation Code)			
	Expiration D	Timer: 00:0 ; FEB-28-2008 Ref	00:00:07:59 maining Operatio	in Troi: 00:00:00	

Figure 5-48: Tools Screen - Activation Period is ON (time limited)



Figure 5-49: Tools Screen - Activation Period is OFF

Expiration Date:

A week before the Expiration Date, a message will appear on the screen indicating: "Your Activation Period is About to Expire. Please contact your area CSA to receive your new activation code. (Expiration Date: MMM-DD-YYYY")(See Figure 5-50).

Once Expiration Date has passed, and if a new activiation code has not been entered, a message will appear indicating: "Your

Activation Period Has Expired. Expiration Date: MMM-DD-YYYY. Please Enter New

Activation Code" (See Figure 5-51).



Figure 5-50: Notification Screen -Activation Period about to Expire



Figure 5-51: Notification Screen - Activation Period about to Expire

Operation Time:

If the Remaining Operation Time is less than 10 hours an indication will appear on the bottom part of **Treatment** screen (See Figure 5-52, circled in red), this indication will turn red when the Remaining Operation Time is 1 hour or less (See Figure 5-53, marked in red).

When Operation Time is over, a message will appear on the screen indicating: "Your Activation Period Has Expired. Please Enter New Activation Code".



Figure 5-52: Treatment Screen – Remaining Operation Time is 10 hours or less



Figure 5-53: Treatment Screen -Remaining Operation Time is 1 hour or less

To reactivate system or extend the **Activation Period** in advance, operator will need to enter a new **Activation Code**. This code will set a new **Expiration Date** or **Operation Time** and will activate the system. Pressing the **Activation Code** button on **Tools** screen will open a new screen indicating "Please Enter Activation Code (Key Number: XXXX)" (See Figure 5-54, Circled in red).

At this point operator is required to contact the local Venus Concept office and provide the 4-digit-key that appears on the top of the screen (e.g. AC60) (See Figure 5-54, circled in red).

The office will then supply a 16-digit **Activation Code**. Operator should enter the code (followed by pressing the **Confirm** button).

Entering the Activation Code correctly will re-enable system operation.



Figure 5-54: Expiration Date

6. Treatment Procedures

Exclusion Criteria

- > Active Inflammation and/or Infection in the Treated Area.
- > Current or History of Cancer & Premalignant Condition.
- > Degenerative neurologic diseases.
- Diseases Stimulated by Heat, (such as recurrent Herpes simplex in the treatment area).
- Internal Defibrillator/Pacemaker.
- > Metal implants in the treated area excluding dental implants.
- > Uncontrolled Disorder of the Thyroid Gland.
- Varicose Veins.
- ➢ Pregnancy, IVF procedure.
- Skin Related Autoimmune Diseases.
- > Silicone implants and injections in treated area.

Precaution Criteria

- Botox injection and implants in the treatment area (wait 1 month after the last injection before starting a treatment).
- Breast feeding.
- > Epilepsy.
- Facial laser resurfacing and deep chemical peeling within the last month, if face is treated.
- > Fresh Scars or Wounds, Scarification of the Skin in the Treated Area.
- Telangicetasia.
- > Thyroid gland not recommended treating over the thyroid gland.
- > Ongoing use of Isotretinoin (e.g. Roaccutane).
- Recent Fillers injection.
- Recent Surgical Procedure/Special Medications.
- Rosacea (not recommended if face is treated. No problem to treat other body areas).

Pre-Treatment

<u>Recommended Accessories</u> - Prior to treatment, it is advised to ensure that you have the following:

- > 1 Jar of Pure Glycerin (liquid for face and gel for body).
- ➤ Weight Scale (Tracking tools to follow the client's progress).
- Measuring Tape (Tracking tools to follow the client's progress).
- Camera & Tripod (Tracking tools to follow the client's progress).

Clinical Data Management

- Establish a detailed client medical history, including previous treatment modalities. This would include, and not be limited to, a questionnaire to ensure that the client does not fall under any of the exclusion criteria.
- Review with client the informed consent form to ensure that he/she is well informed of the treatment and possible side-effects from the treatment.
- Determine why the client is seeking this treatment, you will need to both understand and manage their expectations to ensure a pleasant outcome.

Expected Clinical Effects

- > Mild discomfort associated with the treatment.
- > Heat sensation will be felt both during and following the treatment.
- > Erythema could be present in the treated area for up to 2 hours post procedure.
- Adverse Effect: Skin burn might occur if the operator does not follow instructions, i.e. staying too long with the Applicators on the same spot. If such a burn occurs, it should be treated conventionally.

Documentation

- It is strongly recommended that "Before and After" photographs are taken of the treated area to help document the treatment progress, manage expectations and maximize client satisfaction. Since many clients are not able to see the progress of treatment objectively because it is a slow and gradual change, these photographs help you provide objective evidence of their progress. It is also a great tool for your clinic to have before and after photo's to show other potential clients of the results that they can expect to see. To ensure consistency in the photo's, the following guidelines should be set:
 - Markings should be made on the floor showing exactly where the client should stand for their photos.
 - Ensure that the same camera speed, flash and distance from camera to client are done the same way each time.

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Treatment documents should be kept with information like Body Weight and specific body measurements should be taken before the first treatment. Again to ensure consistency in the measurement of the clients, guidelines should be set on where these measurements should be taken to make sure it is done the same way each time.

Preparing for the treatment

- All Jewelry and/or metal items should be removed from the treated area. This would include if the client has a belly ring, to ensure the safety of the treatment.
- Treated area should be clean and free from lotions, creams and make-up.
- Ensure that the client is relaxed, comfortable and lying down on the treatment bed with the treated area exposed.
- Solution Should then be applied thoroughly to the treated area.

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7. Maintenance

This chapter describes the routine maintenance procedures users should perform: cleaning the various Apparatuses.

All other service/maintenance procedures are to be performed by the company's authorized service personnel ONLY!

For continued protection against fire, replace the fuse ONLY with one of the same type and rating as recommended in this user manual in chapter 9.

Cleaning the System

- Clean and disinfect the applicators after each treatment according to the following procedure:
- To clean the LB2 and LF2 applicators, press the lower suction indicator until CL appears on the screen. The applicators will then spit air to clean any residues left in the system. Perform the cleaning procedure for 30 seconds. (Figure; 7-1)



Figure 7-1: CL Mode

> 7.1.1 Cleaning

Do not immerse the treatment applicator in any liquid.

- 7.1.1.1 Use a soft cloth, moistened with enzymatic detergent solution such as 0.5% ANIOSYME DD1, to clean the applicator until it is visually clean. Use the enzymatic detergent according to manufacturer instructions.
- > 7.1.1.2 Use a soft cloth, moistened with water to remove detergent residuals.

> 7.1.2 Disinfection

- > 7.1.2.1 Use germicide swipes to disinfect the applicator for at least 1 minute.
- > 7.1.2.2 Dry the applicator with a clean cloth.
 - Assure that the applicator is dried from any inflammable substance.
 - Always perform the cleaning procedure prior to disinfection.

Cleaning the Air Filters Unit

- While the air filter of LB2&LF2 Applicators should be replaced once a week (but taking under consideration the usage, therefore if one Applicator was not in use, no need to replace it), the filter cup of both Applicators (LB2&LF2) needs to be checked daily and cleaned according to the amount of dust and debris that accumulates.
- > To clean the air filters unit (see Figure 7-2 to 7-4):
 - 1. Turn the system off.
 - 2. Open the filter door by rotating the knob.
 - 3. Repeat the following for the 2 filters displayed:
 - Open the screw located on the bottom of the filter cup, by turning the screw counter clockwise (See Figure 7-2, circled in red).
 - Dismantle the cup from the filter unit (See Figure 7-3, circled in red).
 - Rinse the cup and ensure it is dried properly.
 - Replace the filter (See Figure 7-4, circled in red).
 - Assemble the system unit back by turning the screw clockwise.



Figure 7-2, Screw Counter



Figure 7-3, Filter Cup



Figure 7-4, Filter

8. Troubleshooting

Failure	Correction
No Power	 Check the power cable. Make sure that the Plug cable is inserted into both the wall socket and the System inlet. Make sure that main switch is in "on" position check if "emergency button" is depressed If the cable is connected properly and still there is no power, contact your local distributor.
No Suction Power	 Clean the filters as describe in section 7-1. To clean the LB2 and LF2 applicators, press the lower suction indicator until CL appears on the screen. The applicators will then spit air to clean any residues left in the system. Perform the cleaning procedure for 30 seconds. (Figure; 7-1) If the filters and LB2 / LF2 applicators are clean and No Suction please contacts your local distributor.
No Display	 Turn the system to its "ON" position on the rear panel. Check the power cable. Make sure that the Plug cable is inserted into both the wall socket and the System inlet. Restart System (turn System off for 2 minutes and then turn System on). If still there is no display, contact your local distributor.
No Energy i Applicators Replacing Applicator in	 Make sure Applicators are connected properly. If the Applicators are connected properly and still there is no energy in Applicators, contact your local distributor. Disconnect existed LF1/LF2/LB1/LB2 Applicators from the rear panel of the system. Connect the LF1/LF2/LB1/LB2 Applicators to the rear
functional fault	panel of the system. This is done by aligning the guiding pins on the LF1/LF2/LB1/LB2 Applicators connector with those in the rear panel of the System. Then slide the connector along the guiding pins until it clicks into place and turn clockwise to lock the connector. Each connector has its own port and will be labeled accordingly.

Failure	Correction
Touch Screen Does Not Respond	 Restart system (turn system off for 2 minutes and then turn System on). If the screen still does not respond, contact your local distributor.
Fuse is blown In the event that you switch "ON" the system and nothing appears on the screen and at the same time the fans located in the rear panel of the system are not working, it is most likely that the main fuse burnt.	 Make sure to disconnect system from wall electricity Above the main switch located on the rear panel, you will find the main switch integrated with a fuse box. Pull the fuse drawer out using a flat screwdriver. Remove the two fuses and check if they are burnt. Replace fuses if necessary as shown on figure below.
The message: " Error - Can't Read Configuration File" appears on the screen	 Restart system (turn system off for 2 minutes and then turn System on). If the message still appears, contact your local distributor.
The message: " Error - Can't Read Configuration File" appears on the screen	 Restart system (turn system off for 2 minutes and then turn System on). If the message still appears, contact your local distributor.
The message: " Error - Can't Read Language File" appears on the screen	 Restart system (turn system off for 2 minutes and then turn System on). If the message still appears, contact your local distributor.

Failure	Correction
The message: "The Machine is Locked - Please Contact Your" appears on the screen	 Restart system (turn system off for 2 minutes and then turn System on). If the message still appears, contact your local distributor.
The message: "End of Treatment - Press Confirm to Continue" appears on the screen	Set treatment time and then press the start button to start treatment.
The message: "Set New Login Code Failed - Please Try Again" appears on the screen	 In order to set new login code, the operator has to enter the new login code twice. If the new login code is not identical in both times - the login code is not replaced. Try to set login code again.
Themessage:"Invalid ActivationCode-PleaseEnterNewActivationCode"appearsonthescreen	 Try to enter the activation code again If the message still appears, contact your local distributor.

Failure	Correction
The message: "Wrong Login Code - Please Try Again" appears on the screen	 Re-enter login code. If you cannot remember your login code you can use the master code "A1B2C3D4" in order to login. It is then recommended that you set your own private login code.
Themessage:"InvalidLoginCode–PleaseEnter8DigitsCode"appears onthe screen	Enter 8 digits code.
The message: "Your Activation Period has Expired – Please Enter New Activation Code" appears on the screen	 Contact your local distributor in order to get new activation code. Press the Tools icon -> Activation Code and enter the new activation code to activate the system.
Themessage:"PleaseNoteYourActivationPeriodhasExpired"appearson the screen	 Contact your local distributor in order to get new activation code. Press the Tools icon -> Activation Code and enter the new activation code to activate the system.
The message: "Remaining Operating Time: ##:##:##" appears on the screen	 Contact your local distributor in order to get new activation code. Press the Tools icon -> Activation Code and enter the new activation code to activate the system.

9. Technical Specifications

Technical Specification 8	& Configurations
Input Voltage	100/120/240V ~, 670VA, 50/60Hz.
Output RF Frequency	1MHz
Fuse	T10A, 250V
Max RF Output Power	Up to 150W
(MP) ² Applicators	LF1 Applicator - Treatment Applicator with integrated thermometer. (detachable accessory) LB1 Applicator - Treatment Applicator with integrated thermometer. LF2 Applicator - Treatment Applicator with 4 suction levels (optional) and integrated thermometer. LB2 Applicator - Treatment Applicator with 4 Suction levels (optional) and integrated thermometer
Output voltage	Up to 130V @ Rated Load
Dimensions	40X40X100 cm (DxWxH)
Weight	40 Kg.

Note: Isolation from supply mains is provided by power inlet.



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10. Manufacturer Warranty

The Company warrants that the product shall be free from defects in materials and workmanship for a period of 1 (one) year from the date of shipment by the Distributor to the purchaser, provided however that in no event shall any warranty extend more than 15 months from the date it was delivered to the local distributor. The liability of the Company under this warranty is limited to the repair or replacement (at Company's sole decision) of any allegedly defective part or parts under warranty at its expense.

The warranty contained herein does not extend to any product that is modified or altered, is not maintained to the Company's maintenance recommendation, is operated, handled or stored in a manner other than that specified by the Company, has its serial number removed or altered, or is treated with abuse, negligence or other improper treatment (including without limitations, use outside the recommended working environment).

The Company makes no warranty in respect to accessories and other parts made by other manufacturers, whether or not warranted by such manufacturers, which have been attached or connected to the product after installation, unless such accessory and other parts have been supplied by the Company.

Please fill your details, scan and e-mail to service@venus-concept.com

Business Name:	
Contact:	
Address:	
Telephone Number:	
Email Address:	
Date Purchased:	
S/N:	